IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

MARK AARON HESS, by and through his parent and natural guardian, MARK HESS	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 08-0229
A.I. DUPONT HOSPITAL FOR CHILDREN, et al.	:	

SURRICK, J. **MARCH 5, 2009**

MEMORANDUM & ORDER

Presently before the Court are the Motion of Defendant William I. Norwood, M.D., Ph.D., for Summary Judgment Pursuant to Rule 56 of the Federal Rules of Civil Procedure (Doc. No. 10), the Motion for Partial Summary Judgment to Dismiss the First Cause of Action (Doc. No. 11), the Motion for Partial Summary Judgment to Dismiss Count II of the Complaint Alleging Fraud and Intentional Misrepresentation and Punitive Damages Claim (Doc. No. 12), the Motion of Defendants for Summary Judgment on Medical Monitoring Claim Set Forth in Count VI (Doc. No. 13), and the Institutional Defendants' Motion for Partial Summary Judgment (Doc. No. 14). For the following reasons, Defendants' Motions will be granted in part and denied in part.

I. BACKGROUND[1]

[1] For purposes of this opinion, we refer to Mark Hess as "Plaintiff"; A.I. duPont Hospital for Children, the Nemours Foundation, the Nemours Cardiac Center, and the Nemours Delaware Institutional Review Board as the "Institutional Defendants"; and Dr. William Norwood and Dr. John Murphy as the "Medical Defendants." In August 2008, Plaintiff settled with defendants NuMed and Allen Tower. (*See* Doc. No. 8.) In December of 2004, when this lawsuit existed as

A. Plaintiff's Medical History

Plaintiff was born on January 8, 2002, with a congenital heart defect known as Hypoplastic Left Heart Syndrome ("HLHS").[2] HLHS is characterized by an underdevelopment of the left side of the heart, preventing circulation of oxygenated blood to the body. Babies born with HLHS cannot survive unless they receive a course of treatment that entails three procedures. The first procedure, called the "Norwood Procedure," modifies the heart's physiology so that the right ventricle, which normally pumps deoxygenated blood to the pulmonary arteries for oxygenation, pumps oxygenated blood to the body. The second and third procedures, respectively called the "Hemi-Fontan" and "Fontan Completion," create a physiology that allows deoxygenated blood to flow to the lungs without first going to the heart. In the Hemi-Fontan procedure, the superior vena cava, which receives deoxygenated blood from the upper body, is redirected to the pulmonary arteries. In the Fontan Completion, the inferior vena cava, which receives deoxygenated blood from the lower body, is redirected to the pulmonary arteries.

Plaintiff was born at a hospital in Tupelo, Mississippi. When it became apparent that Plaintiff had HLHS, the doctors informed Plaintiff's parents that Plaintiff had a "slim chance" of survival. (Doc. No. 11, Ex. D at 54 (M. Hess Dep.).) The doctors presented Plaintiff's parents

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a class action (*see* discussion *infra*), the plaintiffs voluntarily dismissed defendants Dr. Kenneth Murdison and John T. Walsh. *See* Voluntary Dismissal of Action Against Less Than All Parties, *Conway v. A.I. duPont Hosp. for Children*, No. 04-4862 (E.D. Pa. Dec. 20, 2004).

[2] Definitions of medical terms used in this opinion can be found in any one of several readily accessible sources, such as *Stedman's Medical Dictionary* (28th ed. 2006) or Medline Plus, http://www.nlm.nih.gov/medlineplus/mplusdictionary.html.

with three options. (*Id.*) They could take no action and allow Plaintiff to pass away; they could put his name on a heart transplant list and hope that an acceptable transplant became available in time; or they could take him to a hospital at the University of Michigan for the Norwood Procedure. (*Id.* at 54-55.) Plaintiff's parents elected the last option and Plaintiff had the Norwood Procedure performed in Michigan six days after his birth. (Doc. No. 22, Ex. 2 at 2 (hereinafter, "Weber Report").) Following the Norwood Procedure, Plaintiff suffered several complications including seizures and a grade II intraventricular bleed. (*Id.*)

For reasons that are not entirely clear, Plaintiff's parents decided to transfer him to the A.I. duPont Hospital in Wilmington, Delaware. (*See* Doc. No. 11, Ex. E at 62 (hereinafter, "A. Hess Dep.") (implying that Dr. Norwood was the only doctor who would operate on Plaintiff); Doc. No. 18, at 4 (stating that Plaintiff was transferred from the Michigan Hospital to the duPont Hospital because he "experienc[ed] some medical difficulties . . .").) On July 10, 2002, Dr. Norwood performed a Hemi-Fontan procedure on Plaintiff. (Weber Report at 2.) Following the Hemi-Fontan procedure, Plaintiff experienced complications including a pneumothorax, brief episodes of supraventricular tachycardia, mild tricuspid and neoarctic valve insufficiency, and atrial flutter. (*Id.*) These complications necessitated at least one additional hospitalization and two follow-up procedures: an ablation procedure and an electrophysiology study. (*Id.*)

Sometime during 2002, the Medical Defendants determined that the Fontan Completion procedure could be accomplished by implanting a Cheatham Platinum covered stent ("CP stent") via catheterization. The benefit of such a procedure was that it avoided the risks attendant with a open-heart surgery. According to Dr. Norwood, the catheterization procedure "accomplish[es] the identical physiological and structural result as [the surgical procedure], but avoid[s] open

heart surgery in the infant." (Doc. No. 11, Ex. C ¶ 9 (Norwood Aff.).)

On January 13, 2003, Dr. Murphy performed a Fontan Completion on Plaintiff using a catheter and two CP stents. (Weber Report at 2.) Before the procedure, Plaintiff's mother signed two consent forms: one provided by NuMed Inc., the CP stent's manufacturer; and one provided by the Hospital. (*See* Doc. No. 11, Exs. F, G (hereinafter, "NuMed Consent Form" and "duPont Consent Form," respectively).) The NuMed Consent Form informed Plaintiff's parents, *inter alia*, that the CP stent "ha[d] been developed over the past two years and remains in the investigational stage. . ." and that the CP stent "ha[d] not been approved by the United States Food and Drug Administration (FDA) . . . ." (NuMed Consent Form at 1.) The CP stent is a Class III medical device under the Food, Drug & Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, and the Medical Device Amendments, 21 U.S.C. §§ 360 *et seq.* *See* 21 U.S.C. § 360c(a)(1)(C). As a Class III device, the CP stent could not be sold or marketed by NuMed without obtaining premarket approval from the FDA. *See* 21 U.S.C. §§ 331, 351, 360e. The FDA permitted the Medical Defendants to implant the CP stent in Plaintiff on a compassionate use basis. (*See* Doc. No. 19 at 14-15; *id.* Ex. 7.)[3]

After the catheter completion of the Fontan, Plaintiff experienced complications including two small areas of right to left shunting within the stent and a hemothorax (an accumulation of blood in the pleural cavity) that required removal. (Weber Report at 2.) Three days after being discharged from the hospital, Plaintiff was readmitted to treat dehydration and an atrial flutter. (*Id.*) Plaintiff was discharged three days later. (*Id.*) He was readmitted two

[3] *See also* 21 C.F.R. § 812.36; Ctr. for Devices and Radiological Health, FDA, Guidance on IDE Policies and Procedures 19-20 (1998) *available at* http://www.fda.gov/cdrh/ode/idepolcy.pdf.

weeks after that to address a decrease in his blood's oxygen saturation, at which time his doctors observed an additional right to left shunt in the stent. (*Id.*) After several days of observation at the hospital, Plaintiff was discharged. (*Id.*)

Plaintiff currently suffers from a blood platelet disorder known as idiopathic thrombocytopenia purpura ("ITP"). It is not clear whether Plaintiff had ITP at birth, whether he developed it sometime after birth but before his Fontan Completion, or whether he developed it after his Fontan Completion. However, Plaintiff concedes that the ITP is unrelated to the CP stent or treatment he received from the Medical Defendants. (Doc. No. 22 at 6 (acknowledging that Plaintiff "does have an unrelated blood platelet disorder, for which he has had much intense medical care and supervision").) Complications resulting from the ITP have resulted in Plaintiff making numerous hospital visits from November of 2004 through July of 2006. (*Id.*) ITP limits the physical activities in which Plaintiff, who is now seven years old, can engage. For instance, he is not permitted to participate in his school's physical education classes. (A. Hess Dep. at 8.) Despite these limitations, Plaintiff's mother testified that he is doing "amazingly" well. (*Id.* at 94; *see also id.* at 7-8.)

B. Procedural History

Plaintiff brought this lawsuit in 2004 as one of three named plaintiffs to a class action. *See* Complaint, *Conway v. A.I. duPont Hosp. for Children*, No. 04-4862 (E.D. Pa. Oct. 15, 2004). The Complaint alleged a number of torts arising out of the use of the CP stent. *Id.*

In February of 2007, we dismissed several claims against the Medical Defendants for failure to state claims upon which relief may be granted. *See Conway v. A.I. duPont Hosp. for Children*, No. 04-4862, 2007 WL 560502 (E.D. Pa. Feb. 14, 2007) (*Conway I*). Under the broad

scope of negligence alleged in Count I of the Complaint, we dismissed the plaintiffs' failure to warn, failure to perform adequate testing, and negligent marketing and design theories as alleged against the Medical Defendants. *Id.* at *3-5. We determined that the plaintiffs' failure to warn claim amounted to an informed consent theory. *Id.* at *4. We also determined that, to the extent that the plaintiffs' failure to warn theory was based on products liability, there was no legal authority "that would require a surgeon to provide his patient with the same warnings prior to surgery that would be required of the manufacturer of a product." *Id.* Similarly, we determined that the Medical Defendants did not have a duties with regard to the testing and design of the CP stent. *Id.* at *5-6. We dismissed the plaintiffs' assault and battery claim against the Medical Defendants because the Complaint alleged what amounted to an informed consent claim, which in Delaware sounds in negligence and not battery. *Id.* at *8. Finally, we dismissed the plaintiffs' strict products liability and express and implied warranty claims against the Medical Defendants because professionals are not normally liable under these theories and the plaintiffs alleged no facts that would require a deviation from the normal rule. *Id.* at *9-10 (citing and discussing *Golt v. Sports Complex, Inc.*, 644 A.2d 989, 993 (Del. Super. Ct. 1994) with regard to strict liability and *Coleman v. Garrison*, 349 A.2d 8, 11 (Del. 1975), *rev'd on other grounds*, *Garrison v. Med. Ctr. of Del. Inc.*, 571 A.2d 786 (Del. 1989) with regard to express and implied warranties).

On April 13, 2007, a Stipulation was filed dismissing all class action allegations in the Complaint with prejudice. *See* Stipulation and Order, *Conway v. A.I. duPont Hosp. for Children*, No. 04-4862 (E.D. Pa. Apr. 13, 2004). On January 11, 2008, we issued an order that the cases of the three named plaintiffs were to be tried separately and issued separate civil action numbers.

(*See* Doc. No. 1.) Prior to the plaintiffs' request to have their cases tried separately, it became apparent that Plaintiff's parents disagreed over whether they should pursue this litigation. On April 12, 2007, Plaintiff's father filed a petition to be appointed Plaintiff's guardian *ad litem*. *See* Petition of Mark Hess for Appointment of Guardian Ad Litem for Minor Plaintiff, *Conway v. A.I. duPont Hosp. for Children*, No. 04-4862 (E.D. Pa. Apr. 12, 2007). Plaintiff's mother had written a letter to Dr. Norwood expressing gratitude to Dr. Norwood for saving Plaintiff's life and disavowing the lawsuit. (*See* Doc. No. 11, Ex. B.) Plaintiff's father believed that pursuing litigation was in Plaintiff's best interest. On April 17, 2007, after a hearing we appointed Plaintiff's father, Mark Hess, as Plaintiff's guardian *ad litem*. *See* Order, *Conway v. A.I. duPont Hosp. for Children*, No. 04-4862 (E.D. Pa. Apr. 17, 2007).

Recently, we have ruled on summary judgment motions in the related cases of Teague Conway and Molly Guinan. On January 6, 2009, we granted summary judgment in favor of the Defendants on all outstanding claims in the Teague Conway case. *See Conway v. A.I. duPont Hosp. for Children*, No. 04-4862, 2009 WL 57016, at *16-17 (E.D. Pa. Jan. 6, 2009) (*Conway II*). Teague Conway had developed ascites, pleural effusions (conditions characterized by fluid build up in the abdomen and lungs, respectively), and protein losing enteropathy (or "PLE," a condition marked by lose of serum protein through the walls of the intestine) after the completion of the Fontan procedure. *Id.* at *2-3. Teague Conway's parents moved him from A.I. duPont Hospital in Wilmington, Delaware, to the Children's Hospital of Philadelphia ("CHOP"), where his new physicians performed the take-down of his Fontan, which entailed removing the CP stent. *Id.* at *3. The physicians observed a thrombus (a blood clot) lodged in the CP stent. *Id.* at *7. We granted the Defendants' motions for summary judgment because

Teague Conway did not provide medical expert testimony establishing a causal connection between the use of the CP stent and the PLE, ascites, or thrombus as required by Delaware law. *See id.* at *5-7, *10-12.

One month later, we granted summary judgment in favor of the Defendants on all claims except for the medical monitoring claim in the Molly Guinan case. *See Guinan v. A.I. duPont Hosp. for Children*, No. 08-0228, 2009 WL 307019 (E.D. Pa. Feb. 6, 2009) (*Guinan I*); *Guinan v. A.I. duPont Hosp. for Children*, No. 08-0228, 2009 WL 311113 (E.D. Pa. Feb. 6, 2009) (*Guinan II*). Molly Guinan developed PLE and plastic bronchitis (a condition where protein is lost through the lungs) after the completion of her Fontan. *Guinan I*, 2009 WL 307019, at *2. We granted the Medical Defendants and Institutional Defendants' summary judgment motions regarding medical negligence and informed consent for the same reason as in the Teague Conway case: Molly Guinan did not produce medical expert testimony establishing a causal connection between the use of the CP stent and her PLE and plastic bronchitis as required by Delaware law. *Id.* at *10-15. We denied the Medical Defendants and Institutional Defendants' motion for summary judgment on Molly Guinan's medical monitoring claim (*see* medical monitoring discussion *infra*).[4] *See id.* at *16-18. In *Guinan II*, we addressed NuMed's motion for summary judgment, dismissing all outstanding claims against NuMed CEO Allen Tower and dismissing all claims except the medical monitoring claim against NuMed. *See Guinan II*, 2009 WL 311113, at *25-26.

II. LEGAL STANDARDS

[4] The medical monitoring claim in the Teague Conway case was voluntarily dismissed. *See* Stipulation to Dismiss Count VI – Medical Monitoring of Plaintiffs' Complaint, *Conway v. A.I. duPont Hosp. for Children*, No. 04-4862 (E.D. Pa. Sept. 8, 2008).

A. Summary Judgment

A moving party is entitled to summary judgment when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); s*ee also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); *Fed. Home Loan Mortgage Corp. v. Scottsdale Ins. Co.*, 316 F.3d 431, 443 (3d Cir. 2003). Where the non-moving party bears the burden of proof at trial, the moving party may identify an absence of a genuine issue of material fact by "showing" the court that there is no evidence in the record supporting the non-moving party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 325 (1986); *UPMC Health Sys. v. Metro. Life Ins. Co.*, 391 F.3d 497, 502 (3d Cir. 2004). Once the moving party carries this initial burden, the non-moving party must set forth specific facts showing that there is a genuine issue for trial. *See* Fed. R. Civ. P. 56(e)(2) (stating that "an opposing party may not rely merely on allegations or denials in its own pleading; rather, its response must . . . set out specific facts showing a genuine issue for trial"); *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (noting that the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts"); *Watson v. Eastman Kodak Co.*, 235 F.3d 851, 857-58 (3d Cir. 2000) (explaining that once the movant has demonstrated an absence of a genuine issue of material fact, the non-movant must then establish the existence of each element on which it bears the burden of proof); *Ridgewood Bd. of Educ. v. N.E. for M.E.*, 172 F.3d 238, 252 (3d Cir. 1999) (noting that plaintiffs cannot avert summary judgment with speculation or by resting on the allegations in the pleadings). Courts must draw all reasonable inferences from the record in favor of the non-movant. *Knabe v. Boury Corp.*, 114

F.3d 407, 410 n.4 (3d Cir. 1997). Moreover, courts must not resolve factual disputes or make credibility determinations. *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1127 (3d Cir. 1995)

B. Choice of Law

Since this is a diversity action, we must determine which state's laws apply. To do this, we apply the choice of law principles of the forum state. *See, e.g.*, *Thabault v. Chait*, 541 F.3d 512, 521 (3d Cir. 2008) (*citing Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938); *Pennsylvania v. Brown*, 373 F.2d 771, 777 (3d Cir. 1967)); *Warriner v. Stanton*, 475 F.3d 497, 499-500 (3d Cir. 2007) (*citing Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487 (1941)). Pennsylvania courts employ a two-step interest analysis to determine choice of law. *See Griffith v. United Airlines Inc.*, 203 A.2d 796, 806-07 (Pa. 1964); *see also Hanover Ins. Co. v. Ryan*, No. 06-2650, 2007 U.S. Dist. LEXIS 92646, at *9-12 (E.D. Pa. Dec. 17, 2007) (discussing *Griffith*). Under the first step of the analysis, a court must address whether a conflict exists between the laws of the competing states. *Hanover*, 2007 U.S. Dist. LEXIS 92646, at *11. If a conflict exists, then the court must "weigh the interests of each state in the resolution of the dispute, and determine which state has greater contacts with the dispute." *Id.* at *12.

The parties agree that Delaware law governs the outcome of this case on all claims except the claim for medical monitoring. (*See, e.g.*, Doc. No. 11 at 8-9; Doc. No. 21 at 3.) When parties agree as to choice of law, courts often do not engage in a choice of law analysis. *See, e.g.*, *USA Mach. Corp. v. CSC, Ltd.*, 184 F.3d 257, 263 (3d Cir. 1999) (assuming without deciding that Pennsylvania law governed diversity suit where parties appeared to be in agreement on choice of law); *see also Aubrey v. Sanders*, No. 07-0137, 2008 U.S. Dist. LEXIS

74161, at *14-15 (W.D. Pa. Sept. 26, 2008) (declining to engage in choice of law analysis where there was no apparent dispute between the parties regarding choice of law); *Adani Exps. Ltd. v. AMCI Exp. Corp.*, No. 05-304, 2007 U.S. Dist. LEXIS 88969, at *23 (W.D. Pa. Dec. 4, 2007) ("There is no need for a detailed choice of law analysis . . . because the parties agree that Pennsylvania's substantive law governs the issue of contract formation."). In the *Conway* and *Guinan* cases, we determined that Delaware law applied to the plaintiffs' negligence and fraud claims. *See Conway II*, 2009 WL 57016, at *4-5; *Guinan I*, 2009 WL 307019, at *5-8; *Guinan II*, 2009 WL 311113, at *5-6; *see also* 42 Pa. Cons. Stat. § 5101.1(b) ("[A] medical professional liability action may be brought against a health care provider for a medical professional liability claim only in the county in which the cause of action arose."). Those claims arose out of the same wrongful conduct alleged by Plaintiff in this case. Accordingly, we will apply Delaware law to Plaintiff's fraud and negligence claims.

Like the plaintiff in *Guinan*, Plaintiff is a resident of New Jersey. In *Guinan I*, we determined that a conflict existed between the laws of Delaware, Pennsylvania, and New Jersey with regard to the medical monitoring claim in part because it was unclear whether Delaware recognized a medical monitoring cause of action. *See Guinan I*, 2009 WL 307019, at *7-8. After determining that Delaware had the greatest interest in having its policies govern the outcome of the action, we predicted that given the unique circumstances of the plaintiffs in these cases, the Delaware Supreme Court would recognize a medical monitoring cause of action. *Id.* at *16-18. In so doing, the Delaware Supreme Court would necessarily look to other jurisdictions for guidance, including the laws of Pennsylvania and New Jersey. Accordingly, to the extent necessary, we will rely on the laws of all three states for guidance.

III. LEGAL ANALYSIS

A. Negligence

In Delaware, "any tort . . . based on health care or professional services rendered, or which should have been rendered, by a health care provider to a patient," 18 Del. C. § 6801(7), is governed by the Health Care Malpractice Insurance and Litigation Act (the "Health Care Act"), 18 Del. C. §§ 6801 *et seq.* Under the Health Care Act, all such torts are "medical negligence" and parties seeking redress must comply with the Act's requirements. *See* 18 Del. C. § 6801(7); *see also* 18 Del. C. §§ 6850-58. Plaintiff's claims clearly fall within the scope of the Health Care Act since they arise from health care services that Plaintiff received from the Medical Defendants. (*See, e.g.*, Doc. No. 19 at 4-5.) In fact, Plaintiff appears to articulate three separate theories of "medical negligence": a theory based upon substandard care as medical negligence, a theory based upon the lack of informed consent, and a theory based upon the increased risk of harm. The gravamen of these theories is that "'but for' the negligence of the . . . Defendants, Plaintiffs [sic] would not have been subjected to the implantation of the investigational stent" (Doc. No. 21 at 9) and that Plaintiff's "medical future with the stent is unknown" (Doc. No. 22 at 6). In Plaintiff's view, "[h]is claim is about his medical future . . . ." (*Id.* (emphasis omitted).) We address each of Plaintiff's theories separately below; however, there are certain requirements that apply to all three.

Specifically, the Health Care Act mandates that all medical negligence claims be supported by the testimony of a medical expert. *See* 18 Del. C. § 6853(e); *see also* 18 Del. C. §

6854 (setting competency standard for medical experts). The medical expert must opine on two things: (1) how the health care provider deviated from the applicable standard of care and (2) how that deviation caused the alleged personal injury.[5] 18 Del. C. § 6853(e). Plaintiffs who do not satisfy section 6853's expert testimony requirement cannot survive a summary judgment challenge. *See, e.g.*, *O'Donald v. McConnell*, 858 A.2d 960, 960 (Del. 2004) (affirming grant of summary judgment in favor of defendant-physician where plaintiff did not provide expert testimony regarding causation); *Burkhart v. Davies*, 602 A.2d 56, 59-60 (Del. 1991), *cert. denied*, 504 U.S. 912 (1992) (affirming grant of summary judgment to defendants in medical negligence lawsuit because plaintiff had not satisfied "essential element" of producing medical expert testimony as required by 18 Del. C. § 6853); *see also Russell v. Kanaga*, 571 A.2d 724, 732 (Del. 1990) (determining that defendant-physician was entitled to a directed verdict where plaintiff had adduced no expert testimony regarding defendant's deviation from the standard of care); *Wahle v. Med. Ctr. of Del., Inc.*, 559 A.2d 1228, 1233 (Del. 1989) (affirming trial court's dismissal of plaintiff's medical negligence claim for failure to comply with pretrial scheduling orders and her obligation to identify a medical expert pursuant to 18 Del. C. § 6853).

The Health Care Act's requirement that a medical expert must offer testimony regarding causation has two elements. The first is intrinsic to causation: the medical expert must identify

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[5] The Health Care Act lists four exceptions to the expert testimony requirement. *See* 18 Del. C. § 6853(e). Those exceptions are: (1) a "medical negligence review panel has found negligence to have occurred and to have caused the alleged personal injury or death and the opinion of such panel is admitted into evidence"; (2) a foreign object was left in a patient's body; (3) "[a]n explosion or fire originating in a substance used in treatment occurred in the course of treatment"; and (4) "[a] surgical procedure was performed on the wrong patient or the wrong organ, limb or part of the patient's body." *Id.* Plaintiff's claim for medical negligence does not fit into any of these exceptions.

a personal injury that is caused by the medical negligence. Section 6853 specifically provides that plaintiffs must produce medical expert testimony regarding "the caus[e] of the alleged personal injury or death." 18 Del. C. § 6853(e). Without a personal injury there can be no causation and hence no medical negligence claim. The second element is a matter of Delaware policy: a medical expert must testify that the health care provider's deviation from the standard of care was the "but for" cause of the plaintiff's injuries. *See Spicer v. Osunkoya*, No. 8C-04-218, 2008 WL 2955544, at *1 (Del. Super. Ct. Jul. 25, 2008) ("It is well settled that stating that any breach of the applicable standard of care was a 'substantial contributing factor' of Plaintiff's injuries is insufficient. . . . [A]n expert witness [must be] 'prepared to meet Delaware's more rigorous "but for" proximate cause standard.'" (*quoting Ellet v. Ramzy*, No. 4C-03-201, 2004 WL 2240153, at *1 (Del. Super. Ct. Sep. 29, 2004))); *Ellet*, 2004 WL 2240153, at *1 ("It is settled, beyond need for citation, that Delaware rejects the 'substantial factor' causation standard. Delaware steadfastly adheres to the 'but for' standard of causation." (*citing Culver v. Bennett*, 588 A.2d 1094, 1096-97 (Del. 1991); *Edwards v. Family Practice Assocs.*, 798 A.2d 1059, 1065 (Del. Super. Ct. 2002)). The "but for" cause of an injury is the direct cause without which the injury would not have occurred. *See Culver*, 588 A.2d at 1097.

1. Plaintiff's Medical Expert

Plaintiff has produced the testimony of one medical expert, Dr. Howard S. Weber, a board-certified pediatric cardiologist and professor of pediatrics at Penn State University College of Medicine. Dr. Weber offered his opinions regarding this case in a report dated June 18, 2008. The entirety of Dr. Weber's opinion reads as follows:

> [I]t is my opinion that [Plaintiff] underwent transcatheter completion of the Fontan procedure using two non FDA approved Cheatham Platinum (CP) covered stent [sic]

> supplied by Numed corporation without appropriate informed consent. It was below the standard of care at the time, for the parents to not have been informed by the [Medical Defendants] that the CP covered stent had not been previously utilized in this fashion in the United States, was not currently being utilized in a clinical protocol for this particular situation and, in fact, was only being utilized on a "compassionate" use basis for patients undergoing treatment of coarctation of the aorta. The consent was also below the standard of care with respect to informing the parents of the alternatives to the stent procedure since surgical Fontan completion has been the standard of care for many years with excellent early (<30) and late (10-20 years) results. It was also inappropriate and below the standard of care to proceed with such an investigational procedure using a non FDA approved device without appropriate [Institutional Review Board] oversight and approval. I hold these opinions to a reasonable degree of medical certainty.

(Weber Report at 1-2.)

2. Negligence

Plaintiff contends that the Medical Defendants were negligent when they implanted the CP stent in him and that the Institutional Defendants were negligent for not preventing the Medical Defendants from implanting the CP stent. (*See* Doc. No. 21 at 9; Doc. No. 22 at 12-13.) Although Dr. Weber's report creates a genuine issue of material fact with regard to the question of the Medical Defendants' deviation from the standard of care, it is clear that Dr. Weber's report does not contain even the rudiments of an opinion linking the Defendants' deviation from the standard of care to any current condition or malady, or to a condition or malady that is likely to develop in the future. (*See* Weber Report at 2.) Indeed, Plaintiff's mother has testified that Plaintiff is doing amazingly well (A. Hess Dep. at 94) and Plaintiff concedes in his briefing that he is currently "functioning well." (Doc. No. 22 at 6.) Plaintiff's arguments that his claims should survive Defendants' summary judgment challenge seek to persuade us to disregard the Health Care Act's requirement that Plaintiff must produce medical expert testimony identifying a causal connection between the health care provider's deviation from the standard of care and the

patient's personal injury.

As discussed above, Plaintiff's case is the third case to come before us as a result of the use of the CP stent by the Medical Defendants at the A.I. duPont Hospital in the 2002-2003 time-frame. Plaintiff's case presents most clearly the question that underlies all three cases: does the implantation of the CP stent, standing alone, constitute an injury that is sufficient to form the basis of a medical negligence claim under Delaware law? We answered this question in the negative in *Conway* and *Guinan*. However, in *Conway*, the parties focused our attention on the thrombus that necessitated the take-down of the plaintiff's Fontan. *See Conway II*, 2009 WL 57016, at *10. We determined that the plaintiff's medical expert had not stated an opinion that the CP stent or catheterization procedure caused the thrombus or resulted in the need for the take-down of the plaintiff's Fontan. *Id.* at *10-11. In *Guinan*, the primary focus was on conditions that the plaintiff had developed after the CP stent was implanted. *Guinan I*, 2009 WL 307019, at *11-14. We determined in *Guinan* that the plaintiff had failed to produce medical expert testimony that the conditions that she identified were caused by or a result of the CP stent or catheterization procedure. *Id.* at *13-14.

The result is the same here. Plaintiff's medical expert does not identify any complication or conditions caused by the CP stent. Thus, there is neither causation nor injury, and Plaintiff's medical negligence claim cannot survive summary judgment. *See, e.g.*, *Brzoska v. Olson*, 668 A.2d 1355, 1362 (Del. 1995) (stating that absent physical injury plaintiff "could not recover under a negligence theory"); *see also Svindland v. A.I. DuPont Hosp. for Children of Nemours Found.*, No. 05-0417, 2006 WL 3209953, at *5-6 (E.D. Pa. Nov. 3, 2006) (applying Delaware law and granting the defendant's summary judgment motion on the plaintiff's medical

negligence claim against defendant-hospital because the plaintiff's medical expert did not opine on causation).

Plaintiff points to evidence of a January 26, 2004 report prepared at NuMed's behest by a company called MedTrials, Inc. (Doc. No. 19, Ex. 5 at 3 (hereinafter, "MedTrials Report").) The MedTrials Report contains a review of the eighty-two patients at seventeen clinical sites who had the CP stent implanted for various reasons, including Fontan completion, in the 1998 to 2003 timeframe. Plaintiff cites to the MedTrials Report for the proposition that "stents implanted by defendants were associated with numerous adverse events experienced by children after the stents were implanted." (Doc. No. 19 at 12.) The MedTrials Report notes that "Fontan patients appear to have an extremely high complication and stent failure rate." (MedTrials Report at 12.) However, it goes on to recommend "comparison of this rate to that of traditional correction procedures designed to generate appropriate rationale for use of the CP stent in this patient population." (*Id.*) No such comparison appears in the report or in any portion of the record brought to our attention by Plaintiff.

Furthermore, the MedTrials Report cannot serve as a substitute for expert testimony. Such a substitution is not permitted by the Health Care Act. *See* 18 Del. C. § 6853(e) (stating that "there shall be no inference or presumption of negligence on the part of a health care provider" absent the testimony of a medical expert or one of the enumerated exceptions listed in section 6853). The Report does not purport to establish causation in Plaintiff's case and Dr. Weber did not rely upon it in preparing his report. (*See* Weber Report at 1.)

3. Informed Consent

Plaintiff contends that the Medical Defendants did not provide him with the information

necessary to give his informed consent to the CP stent procedure. (*See* Doc. No. 21 at 9; Doc. No. 22 at12-13.) Informed consent is statutorily defined in Delaware as:

> [T]he consent of a patient to the performance of health care services by a health care provider given after the health care provider has informed the patient, to an extent reasonably comprehensible to general lay understanding, of the nature of the proposed procedure or treatment and of the risks and alternatives to treatment or diagnosis which a reasonable patient would consider material to the decision whether or not to undergo the treatment or diagnosis.

18 Del. C. § 6801(6); *see also* 18 Del. C. § 6852 (outlining requirements of an informed consent claim). Informed consent claims in Delaware sound in negligence, not battery. *Brzoska*, 668 A.2d at 1365-66 (noting that informed consent is statutorily defined in the Health Care Act, 18 Del. C. § 6801(6), and is thus a negligence action unless a physician "obtains the consent of the patient to perform one procedure and the physician instead performs a substantially different procedure for which consent was not obtained"). Because informed consent claims sound in negligence, plaintiffs who pursue inform consent claims must satisfy section 6853's expert testimony requirement. *See Valentine v. Mark*, No. 2C-12-244, 2004 WL 2419131, at *3 (Del. Super. Ct. Oct. 20, 2004) (noting that because the informed consent statute, 19 Del. C. § 6852, is found in the Health Care Act, informed consent claims require medical expert testimony regarding causation); *Patten v. Freedman*, No. 83C-NO-61, 1989 WL 64116, at *3 (Del. Super. Ct. May 18, 1989) ("An action based on lack of informed consent is an action for malpractice, and malpractice is defined by a negligence standard. . . . In a negligence action, a plaintiff must show that a negligent act by the defendant proximately caused an injury to the plaintiff.").

Dr. Weber's report contains an opinion regarding Defendants' deviation from the standard of care, satisfying the first requirement of section 6853. He states that Plaintiff underwent the procedure "without appropriate informed consent" and that "[i]t was below the

standard of care at the time, for the parents to not have been informed by the physicians at the A.I. Dupont hospital that the CP covered stent had not been previously utilized in this fashion in the United States, [and] was not currently being utilized in a clinical protocol for this particular situation." (Weber Report at 2.) Thus, there is a genuine issue of material fact for a jury to consider regarding the standard of care. However, the report does not offer any opinion regarding causation. Accordingly, there is no issue of fact for a jury to determine and Defendants are entitled to summary judgment.[6]

Plaintiff directs our attention to evidence in the record that Plaintiff may need to undergo a catheterization procedure to expand the diameter of the CP stent to accommodate growth. (Doc. No. 18 5-6, 12-14; Doc. No. 19 at 5; Doc. No. 22 at 6.) While Plaintiff may need to have the CP stent re-dilated in the future, the re-dilation procedure was an intended part of the course of treatment. (*See, e.g.*, Doc. No. 18 at 14 (citing Dr. Murdison's testimony stating that "[p]resumably, when patients reach some size, much greater than their current size at the time of deployment, we would anticipate re-dilating the stents") (*quoting* Dep. of Dr. Kenneth Murdison at 51-53).) Accordingly, the issue is one of informed consent, and the focus is whether Plaintiff's parents were told of the need for this future procedure. At this procedural juncture, Plaintiff must "go beyond the pleadings and by h[is] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Celotex*, 477 U.S. at 324 (*quoting* Fed. R. Civ. P. 56(e)); *see also* Fed. R. Civ. P. 56(e)(2) (prohibiting non-moving party from "rely[ing] merely on allegations or

[6] We note that a different result might obtain in a jurisdiction where informed consent sounds in battery.

denials in its own pleading"). He has not done so. Plaintiff directs us to no portion of the record that would create an issue of material fact regarding the future catheterization. He cites to no testimony or affidavits from his parents stating that they were not told that a subsequent catheterization procedure to expand the CP stent would be necessary. Indeed, he does not attempt to argue that his parents were not informed. In fact, Plaintiff directs us to testimony in the record that suggests that information regarding the need for a follow-up procedure was conveyed to the families of patients who received the CP stent. (Doc. No. 18 at 14 (citing Dr. Murdison's testimony stating that he "would tell [his patients'] families . . . that this stent would go in at a size that was appropriate for the patient's size at the time of deployment, but we would require a re-dilation as the patient grew") (*quoting* Dep. of Dr. Kenneth Murdison at 51-53).)

4. Increased Risk

Plaintiff appears to argue that Defendants' negligence has placed him at an increased risk of harm. Plaintiff asserts that "[h]is claim is about his medical future." (Doc. No. 22 at 6 (emphasis in omitted); *see also* Doc. No. 18 at 8 n.6 (discussing increased risk theory); Doc. No. 19 at 5.) The Delaware Supreme Court has recognized the increased risk doctrine; however it has specifically limited the theory to damages. *See United States v. Anderson*, 669 A.2d 73, 78 (Del. 1995) (noting that increased risk is "merely one element of damages when negligence has caused harm"). To apply the increased risk doctrine, there must be "a present injury which has resulted in an increased risk of future harm." *Id.* at 77 (*quoting Petriello v. Kalman*, 576 A.2d 474, 484 (Conn. 1990)). Plaintiff has identified no present injury, and his claim fails on that basis. Plaintiff's claim also fails because his medical expert has not identified any increased risk to which Plaintiff is now subject.

In *Anderson*, a military doctor failed to timely identify the plaintiff's cancer, which increased the chance of recurrence of the cancer from zero to fifteen percent. *Id.* at 75. The United States District Court for the District of Delaware certified to the Delaware Supreme Court the question of whether the plaintiff's increased risk for cancer was recoverable as damages. *Id.* at 74. For purposes of the certified question, it was undisputed that the doctor's negligence had caused plaintiff's cancer to spread, thus creating a present injury, and had also caused an increased risk of recurrence. *Id.* at 74-75. The requirement of causation and of present injury were necessary preconditions in the court's reasoning. As the court explained, "[t]his approach addresses concerns about speculative claims for future harm. The requirement of a preceding physical injury prohibits plaintiffs from claiming that exposure to toxic substances, for instance, has created an increased risk of harm not yet manifested in a physical disease." *Id.* at 77. Plaintiff's case here is analogous to the court's hypothetical. Plaintiff has the CP stent in his body, but there is no present injury.

Moreover, Plaintiff has not offered evidence that he is subject to an increased risk of injury in the future. In the case of *Kern ex rel. Kern v. Alfred I. Dupont Institute of Nemours Foundation*, the Delaware Superior Court explained the level of detail with which plaintiffs must support their increased risk theories. No. 2C-05-001, 2004 WL 2191036, at *4 (Del. Super. Ct. Jul. 30, 2004). After reviewing a number of increased risk cases, including *Anderson*, the court stated:

> [A] common element of the cases presented above is that every plaintiff proffered expert opinion specifically quantifying the increased risk or loss of chance caused by the medical negligence. Here, no expert will state with reasonable probability and precision what the chances were that the surgery would have worked, much less offer any opinion as to the percentage by which Defendant's alleged negligence reduced the chance of success. The percentages are vital because they form the basis for any

damages calculation by the jury. Without them, the jury would be left to speculation. *Id.* Assuming a present injury, Plaintiff's increased risk theory still fails because, like the plaintiff in *Kern*, he has not produced any evidence that he is at an increased risk for anything, let alone medical expert testimony that he is a certain percentage more likely to suffer a certain affliction as a result of the CP stent. *See id.* As we noted in *Guinan I*, an unknown future is not a legally cognizable injury. *See* 2009 WL 307019, at *13 (*citing Laskowski v. Wallis,* 205 A.2d 825, 826 (Del. 1964); *Deleski v. Raymark Indus., Inc.*, 819 F.2d 377, 380 (3d Cir. 1987)).

B. Fraud

Plaintiff alleges that the Medical Defendants engaged in a series of fraudulent conduct in order to achieve their goal of implanting the CP stent in their patients. (*See generally* Doc. No. 19 at 3-5.) Despite the far-ranging nature of Plaintiff's fraud allegations, they are "based on health care or professional services rendered, or which should have been rendered, by a health care provider to a patient" and are therefore subsumed by the Health Care Act.[7] *See* 18 Del. C. § 6801(7). *Cf. Miller v. Spicer*, 822 F. Supp. 158, 171 (D. Del. 1993) (noting that claims of breach of implied contract are prohibited by the Health Care Act). Plaintiff cannot proceed with a fraud theory based on health care services rendered when he cannot point to evidence in the record that creates a genuine issue of material fact regarding causation and injury. Accordingly, Defendants

[7] We addressed the viability of fraud claims arising from the provision of medical care at length in *Conway II*. *See* 2009 WL 57016, at *13-16. We determined that fraud claims are subsumed by the Health Care Act's definition of negligence. *See id.* at *15 & n.24 (noting that New York and New Jersey have similarly limited fraud claims arising from the provision of medical services and citing *Spinosa v. Weinstein*, 168 A.2d 32 (N.Y. App. Div. 1991); *Howard v. Univ. of Med. and Dentistry of N.J.*, 800 A.2d 73, 81-82 (N.J. 2002); *Detwiler v. Bristol-Myers Squibb Co.*, 884 F. Supp. 117, 119 (S.D.N.Y. 1995)).

are entitled to summary judgment on Plaintiff's fraud claim.[8]

C. Medical Monitoring

Defendants request summary judgment on Plaintiff's medical monitoring claim because "there is no expert opinion that the stent is hazardous, that there is an increased risk of a serious latent disease, or that a reasonable physician would prescribe a monitoring program different than the one that would have been prescribed for him and his underlying heart conditions anyway." (Doc. No. 13 at 1.) In Defendants' Reply Brief in support of their Motion, they emphasize that to support a medical monitoring claim, Plaintiff must demonstrate that he needs a medical monitoring regime different from what he would have needed absent implantation of the CP stent. (*See* Doc. No. 27 at 1, 5.) Defendants do not contest the fact that Plaintiff requires monitoring. In fact, as we noted in *Guinan I*, Defendants actually recommended that patients who had CP stents implanted at the A.I. duPont Hospital join a registry and receive regular medical exams. *See* 2009 WL 307019, at *16-17. Plaintiff is part of that registry and Dr. Samuel S. Gidding, a cardiologist at the A.I. duPont Hospital, regularly examines Plaintiff. (*See* Doc. No. 27, Ex. B ¶¶ 5-10.)

In *Guinan I*, we predicted that the Delaware Supreme Court would recognize a claim for medical monitoring if presented with the record then before us. 2009 WL 307019, at *17

[8] Defendants also seek summary judgment on Plaintiff's punitive damages claim. (*See* Doc. No. 12 at 11-12.) Punitive damages are generally not available absent compensatory damages. *See, e.g.*, *Franklin Inv. Co. v. Smith*, 383 A.2d 355, 358 (D.C. 1978) ("[P]unitive damages may not be awarded where there is no basis for an award of compensatory damages."). Delaware applies this standard. *Pipher v. Burr*, No. 96C-08-011, 1998 WL 110135, at *4 (Del. Super. Ct. Jan. 29, 1998) ("[W]here compensatory damages are not available, punitive damages are also not available."). Accordingly, granting Defendants' summary judgment regarding punitive damages is appropriate.

(discussing *Mergenthaler v. Asbestos Corp. of Am.*, 480 A.2d 647, 651 (Del. 1984)). Two considerations greatly influenced our prediction. First, the CP stent was a Class III device that was not approved by the FDA when the Medical Defendants implanted it in the plaintiff. *Id.* at *18 (discussing CP stent's status as an unapproved Class III medical device under 21 U.S.C. § 360c(a)(1)(C)). Second and more importantly, Defendants acknowledged that medical monitoring was necessary. *Id.* (noting that Defendants' suggestion that the plaintiff receive medical monitoring was "compelling, if not conclusive, evidence that medical monitoring is appropriate"; citing *Friends for All Children, Inc., v. Lockheed Aircraft Corp.*, 746 F.2d 816, 824 (D.C.Cir.1983), in which defendant's concession that plaintiffs should receive medical monitoring was a basis for the court's decision to recognize a medical monitoring tort). Both of those considerations are present here.

The only noteworthy distinction between Plaintiff and the plaintiff in *Guinan* is that Plaintiff currently receives monitoring treatment from the A.I. duPont Hospital. This difference does not alter our analysis. We agree with Plaintiff that his "right to medical monitoring is not met or limited by his participation in a registry set up by" Defendants. (Doc. No. 18 at 1.) Accordingly, Defendants are not entitled to summary judgment on Plaintiff's medical monitoring claim.

Our determination that Plaintiff's medical monitoring claim survives summary judgment may appear contradictory to our determination that Plaintiff's negligence claims fail because Plaintiff has not identified evidence in the record that creates a genuine issue of material fact that he has suffered any injury caused by Defendants' conduct. Clearly, Plaintiff's medical monitoring claim is "based on health care or professional services rendered" and should thus be

held to the requirements of the Health Care Act, including the Act's expert testimony requirement. *See* 18 Del. C. § 6801(7). Dr. Weber does not address Plaintiff's medical monitoring needs in his report. (*See* Weber Report at 2.) Nevertheless, Defendants have conceded the need for medical monitoring. Therefore, there are issues for a finder of fact to determine, such as whether the monitoring that Plaintiff currently receives is appropriate given his medical history.

As discussed above, the Delaware Supreme Court in *Anderson* voiced concern about the potentially speculative nature of increased risk theories of negligence. *See* 669 A.2d at 77. Moreover, the Delaware Superior Court in *Kern* noted that absent medical expert testimony detailing a patient's increased risks in percentages articulated with "reasonable probability and precision," increased risk theories were too speculative to go before a jury. 2004 WL 2191036, at *4. Based upon these concerns and others, we concluded that the granting of Defendants' motion for summary judgment on Plaintiff's negligence claim was appropriate. However, in the context of this case, there is a difference between a medical monitoring tort and an increased risk theory of negligence. Recognizing a medical monitoring claim here is an effective way to balance the speculative nature of future complications that may be caused by the CP stent with the fairness and efficiency goals that have formed the basis for recognition of a medical monitoring tort by courts across the country. *See, e.g.*, *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 139-40 (3d Cir. 1998) (Scirica, J.) (noting that where "'other sorts of recovery may prove difficult, immediate compensation for medical monitoring needed as a result of exposure'" may be appropriate (*quoting Redland Soccer Club v. Dep't of the Army*, 548 Pa. 178, 696 A.2d 137 (Pa. 1997)); *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 575 (6th Cir. 2005) ("[T]here is

something to be said for disease prevention, as opposed to disease treatment. Waiting for a plaintiff to suffer physical injury before allowing any redress whatsoever is both overly harsh and economically inefficient."); *see also Friends for All Children*, 746 F.2d at 825 (invoking "commonly shared intuitions of normative justice which underlie the common law of tort" as a basis for recognizing a medical monitoring tort). Concerns about speculation are minimized by the fact that the remedy for a medical monitoring claim is "only the quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm."[9] *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 850 (3d Cir. 1990). *Cf. Friends for All Children*, 746 F.2d at 826 (noting that "[i]n the absence of physical symptoms, emotional distress caused by potential risk may . . . be thought too speculative to support recovery"). A jury need not attempt to quantify vague probabilities; it only needs to determine the costs of monitoring.

D. Counts Three, Four, and Five of the Complaint

In *Conway I*, we dismissed Plaintiff's Assault and Battery Claim (Count III), Strict Liability Claim (Count IV), and Breach of Express and Implied Warranties Claim (Count V) against the Medical Defendants. 2007 WL 560502, at *12-13. We dismiss Counts III, IV, and V against the Institutional Defendants based on the rationale discussed in *Conway I* for dismissing those claims against the Medical Defendants.

IV. CONCLUSION

For the foregoing reasons, Defendants' motions for summary judgment will be granted in part and denied in part.

An appropriate Order follows.

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[9] In *Guinan I*, we interpreted this language to mean that punitive damages are not available with medical monitoring claims. 2009 WL 307019, at *18 n.10.

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

MARK AARON HESS, by and through his parent and natural guardian, MARK HESS	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 08-0229
A.I. DUPONT HOSPITAL FOR CHILDREN, et al.	:	

ORDER

AND NOW, this 5th day of March, 2009, upon consideration of the Motion of Defendant William I. Norwood, M.D., Ph.D., for Summary Judgment Pursuant to Rule 56 of the Federal Rules of Civil Procedure (Doc. No. 10), the Motion for Partial Summary Judgment to Dismiss the First Cause of Action (Doc. No. 11), the Motion for Partial Summary Judgment to Dismiss Count II of the Complaint Alleging Fraud and Intentional Misrepresentation and Punitive Damages Claim (Doc. No. 12), the Motion of Defendants for Summary Judgment on Medical Monitoring Claim Set Forth in Count VI (Doc. No. 13), and the Institutional Defendants' Motion for Partial Summary Judgment (Doc. No. 14), and all papers submitted in support thereof and in opposition thereto, it is ORDERED as follows:

1. Motion of Defendant William I. Norwood, M.D., Ph.D., for Summary Judgment is GRANTED as to all claims except the claim for medical monitoring;
2. The Motion for Partial Summary Judgment to Dismiss the First Cause of Action is GRANTED;
3. The Motion for Partial Summary Judgment to Dismiss Count II of the Complaint Alleging Fraud and Intentional Misrepresentation and Punitive Damages Claim is

GRANTED;

4. The Joint Motion of Defendants for Summary Judgment or Alternatively for Partial Summary Judgment on Medical Monitoring Claim Set Forth in Count VI is DENIED;

5. The Institutional Defendants' Motion for Partial Summary Judgment is GRANTED.

IT IS SO ORDERED.

BY THE COURT:

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R. Barclay Surrick, Judge